

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Quality Control Laboratory

Part 1	General information	
Inspected laboratory details		
Name of Laboratory	National Institutes for Food and Drug Control (NIFDC)	
Address of inspected laboratory site	No 31, Huatuo Avenue, Daxing Biomedical Complex, Daxing District, Beijing, 102629, China	
Inspection details		
Dates of inspection	27-30 August 2018	
Type of inspection	Routine inspection	
Introduction		
Brief description of testing activities	Type of Analysis	Finished Products
	Physical/Chemical analysis	pH, water content (Karl Fischer), Loss on Drying, Dissolution, Uniformity of dosage (mass or content)
	Identification tests	HPLC (includes UV, PDA, Fluorescence and Electrochemical detectors), Spectrophotometry (includes UV-Vis, Atomic Absorption and Fourier Transform Infra-Red), Basic Test (include Thin Layer Chromatography, coloring reaction, and precipitation reaction)
	Assay, impurities and related substances	HPLC (includes UV, PDA, Fluorescence and Electrochemical detectors), Spectrophotometry (includes UV-Vis, Atomic Absorption and Fourier Transform Infra-Red), Basic Test (include Thin Layer Chromatography, coloring reaction, and precipitation reaction)
General information about the laboratory	The National Institutes for Food and Drug Control (NIFDC) are in charge of the national quality control of pharmaceutical products in China and are directly affiliated to the State Drug Administration (formerly known as National Medical Products Administration, NMPA). The NIFDC receives financial budget and organizational supports from the SDA.	
History	The first inspection was performed by WHO inspection team within the Prequalification procedure in April 2012. The routine reinspection was performed in October 2013 by WHO PQ inspection team. Since then, the laboratory had been relocated to Daxing District. This is the third PQ inspection of NIFDC on a new facility.	

	NIFDC had received several technical assistance visits organized by WHO-PQ and other agencies to prepare it for prequalification. NIFDC has been accredited according to ISO 17025 by China National Accreditation Service for Conformity Assessment (CNAS) since 2002.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Physical, chemical, instrumentation, bacterial endotoxin (LAL testing) and biological assay of antibiotics laboratories of the Institute for Chemical Drug Control (the Division of Chemical Drug, Division of Antibiotics, Division of Narcotics, and the Division of Pharmacology)
Restrictions	Microbiology laboratory responsible for the testing of microbial limit test and sterility test was out of the scope of this inspection.
Out of scope	The following Divisions within the Institute for Chemical Drug Control namely: the Division of Biochemical medicines, Division of Hormones, Division of micro-organisms, and the Division of Radio-pharmaceuticals were not inspected
Abbreviations	Meaning
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GMP	Good manufacturing practices
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
KF	Karl Fisher titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
NC	Non conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis

SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometry or spectrophotometer

Part 2	Summary of the findings and comments
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1. Organization and Management

The National Institutes for Food and Drug Control (NIFDC) are in charge of the national quality control of pharmaceutical products in China and are directly affiliated to the National Medical Products Administration (NMPA). The NIFDC receives financial budget and organizational supports from the SDA.

NIFDC was headed by the Director-General Dr Li Bo. The Quality Manager was Mr. Zou Jian (Deputy Director-General). There were four Deputy Directors. Dr Zhang Zhijun (Deputy Director) and Professor Zhang Qingsheng (Director) were directly in charge of the Institute for Chemical Drug Control.

The opening meeting started with the introduction of participants by the Director General. Presentation was made by the director, center of quality management in Chinese which was translated into English by the interpreter. The presentation was divided into

- Organization and responsibility of NIFDC
- Brief introduction to quality management system
- Review of WHO PQ of the Institute for Chemical Drug Control.

From the opening meeting presentation, it was noted that the NIFDC was responsible for the following activities:

- a) Pre-marketing testing and technical review of drugs and medical devices for approval
- b) Post-marketing surveillance testing, contract testing, sampling testing, and safety evaluation of drug, medical devices, health food, cosmetics, and testing for food safety of the catering industry
- c) Retesting of drug and medical devices.
- d) Technical review and verification of specification, guidelines and testing procedures for drugs, medical devices; and for food safety.
- e) Research, preparation, characterization and distribution of national reference standards for drugs and medical devices.
- f) Testing of bacterial (viral) strains, collection, identification, preservation, distribution and management of medical standard bacterial (viral) strains and cell strains.
- g) Providing technical assistance and guidance regarding laboratory testing technology for the food and drug quality control institutes nationwide; and organizing the activities to provide technical assistance to the drug testing analysts from the drug research, production operation organizations and medical institutes.

- h) Research and lab investigation of the severe side effect regard with drug and medical devices.
- i) Organize the international collaboration and cooperation in the field of testing and analysis of drug, medical devices, healthy food, cosmetics, and testing and analysis on food safety for the catering industry.

The organizational structure of NIFDC showed a total 12 Institutes, two Research Centres and nine departments. The WHO prequalification inspection focused on the Institute for Chemical Drug Control. This Institute had 8 Divisions, of which 4 Divisions, namely: the Division of Chemical Drug, Division of Antibiotics, Division of Narcotics, and the Division of Pharmacology had applied for the WHO PQ. The remaining four Divisions within the Institute for Chemical Drug Control namely: the Division of Biochemical medicines, Division of Hormones, Division of micro-organisms, and the Division of Radio-pharmaceuticals had not applied for WHO PQ and were therefore outside the scope of this inspection.

The milestones of Quality Management System (QMS) were presented, which showed WHO PQ NIFDC first applied for WHO PQ in 2010, received several technical assistance from WHO and had undergone WHO PQ inspection in 2012 and 2013 in the old location.

It should be noted that the NIFDC re-located to the new premises in 2016 and this report is for the first WHO PQ inspection in these new premises. The old premises were said to be undergoing renovation so as to be used as microbiology laboratories.

Issues noted from this section have been addressed and will be verified during future inspections.

2. Quality management system

Quality Manual / QM had been submitted to WHO PQ prior to the start of the inspection. It was noted that the QM has been revised after the CNAS audit. The major change made in the QM following the visit made by the CNAS in July 2018 pertained to the proficiency testing scheme (ISO 17043). It included the addition of the proficiency testing scheme (PTS) requirement and more details in quality objective, analysts following WHO GPPQCL for drug testing lab, testing related staff familiarized with quality manual, delegation of authority in written form, job description for staff taking part in PTS.

The quality manual was briefly discussed with the NIFDC colleagues. The quality manual contained quality policy statement, organization chart, training requirements and other elements as recommended under 2.2 of GPPQCL. The procedures were cross-referenced and verified. However, the Quality Manual did not have a corresponding table of sections in the Manual and sections in the WHO GPPCL, for easy reference.

Internal audit procedure was discussed. The internal audits were conducted once every year. In addition, internal audits are conducted prior to WHO and other inspections / visits. A list of qualified auditors was maintained. The list is not periodically revised. Also, list did not provide any information pertaining to internal auditors (17025) last training on ISO/IEC standard. The training record of Ms. Wang Ming Juan (internal auditor from Traditional Chinese Medicines /TCM) was briefly reviewed. She received the training from the CNAS between 19th and 21st October 2015. The internal audit process starts from the issuance of notice, audit plan, names of auditors and checklist prepared in accordance with GPPQCL 21 clauses. From the discussion, it was noted that the laboratory did not retain or provide raw data / initial observations recorded during an internal audit. A typed report was prepared retrospectively.

The recent internal audit was performed from 12th to 20th June 2018. The observations were categorized into normal and severe. Six non-conformities were reported during the recent audit and all were categorized as “normal”. The inspection team failed to understand why non-conformity pertaining to “standalone computer systems” was categorized as “normal”. The last internal audit was performed for chemical and drug institute on 23 November 2017. The corrective and preventive actions are implemented manually and system was in place for effective implementation. Quality work plan of 2018 for the NIFDC was in place which included internal audit as per ISO/IEC 17025:2005, PTS, reference materials providers. As such, there was no internal audit schedule available.

Management review (MR) procedure was reviewed. MR was undertaken only once every year. The meeting was organised with the Director General, Management Representative, and included changes, competence of staff, quality policy, changes of technical competence, operation of system, changes of personnel & training, allocation of equipment & instruments, internal & external audits, CAPA, complaints on quality, abnormality of PTS participated, OOS handling, supplier’ evaluation and maintenance of the facility, prediction on workload, analytical report, document review, deviations, client survey & feedback, reference materials, laboratory safety, review of lab animal etc. The last MR was done on 12th January 2018 for the year 2017. The meeting was attended by the Director General (DG), two deputy DGs, Head QMS and several others from different departments (medical device, reagents, food, drugs).

From a quick review of the minutes of the management review meeting, it was noted that a number of items (such as safety, PTS, competence of personnel, quality management system etc.) were discussed as per SOP.

Proficiency testing scheme (PTS): Inter-laboratory comparison and proficiency testing procedure was discussed. Another document (PD-013 procedure on the management of the QC activities) also provided some information on PTS. It was noted that NIFDC participates in the PTS organized by the CNAS, CNCA and international organizations (WHO, LGC, FIP). The analysts who routinely perform certain tests are selected for PTS. The experience learnt from this process is shared with rest of the colleagues in the team.

The 2018 quality control activities schedule including external QC activities referring to PTS was available. It was noted that the laboratory participates in PTS primarily organized by CNAS. The 2018 schedule did not include interlaboratory comparison using international PTS providers such as WHO, EDQM. In 2017, the NIFDC took part in the External Quality Assurance Assessment Scheme Phase 8 (EQAAS 8.1 & 8.2) organized by WHO for assay by HPLC (z-Score -0.5) and related substances by HPLC (z-Score -0.9 for Clindamycin B and z-Score 0.3 for Impurity C). In addition, NIFDC also participated in an endotoxin (LAL) test organized by Charles-River and performance was satisfactory.

Complaint handling procedure was discussed. The complaints are received by phone, email and in person and logged into log sheets. The Quality Management Centre is responsible for the investigation of complaints. No specific timelines were set for the investigation and for the closure of the complaints. It was noted that procedure did not use any tools for the investigation of complaint. Also, there was no system in place for trending of complaints. In 2018, total of 3 complaints were received whereas in 2017, one complaint, and in 2016 two complaints received.

Issues noted from this section have been addressed and will be verified during future inspections.

3. Control of documentation

The laboratory is using a software for the management of documents of internal origin. The software NIFDC management system for quality management system was jointly developed by the NIFDC and external engineers. It was claimed that the system had been qualified before its implementation. The system covered the whole document life cycle from drafting, review and approval; to revision and archival of superseded documents. The documented procedures as required under 2.3 of GPPQCL were verified and found to be available.

Documents of external origin were controlled outside the document software system, as soft copies obtained from the relevant Websites by each department. A list of such documents for the quality management department was reviewed by the inspectors and found to contain the necessary information to enable control of the documents that were mainly received from cnas.org.cn, who.int, sda.gov.cn, and others.

In addition, a Laboratory Safety in Chinese was also available.

Issues noted from this section have been addressed and will be verified during future inspections.

4. Records

A high-level Working Procedure for Records Control and a Working Procedure for Data Control were available. Specific forms e.g. worksheets, etc., were issued and filled and the records generated for each sample tested were kept batch-wise, in the archives room.

Issues noted from this section have been addressed and will be verified during future inspections.

5. Data processing equipment

The Agilent and Shimadzu HPLCs, GC and MS were connected to acquisition network servers (Waters LAC/E³²). All data collected was kept on the server at the Information Center. An SOP for Electronic Data backup was available.

However, the DIONEX and Waters HPLCs were stand-alone versions. The audit trail function was enabled on most HPLCs except for one HPLC. A procedure for Manual Integration was available but manual integration was said not to be allowed. The date and time on the Empower 3 software system all the Chromatography workstation were secured (blocked) from wilful or accidental change by the analyst. However, the date and time on the Windows operating system was not.

Issues noted from this section have been addressed and will be verified during future inspections.

6. Personnel

There appeared to be an adequate number of personnel with the required experience. Personnel training included orientation, skill training, and academic education. Job descriptions and qualification approval system in terms testing techniques were said to be done as per SOP for Job Position Training, Evaluation and Qualification but this was not verified during the inspection.

The total staff in the entire NIFDC were 1,344 (175 PhDs; 375 master's degree and 478 bachelor's degree, and others). The Institute for chemical drug control was reported to have approximately 74 employees (see table below).

Category of Staff	Number of staff
Supervisors	14
Analysts in Chemical Sector	40
Technicians in Chemical Sector	5
Analysts in Microbiological Sector (LAL)	6
Quality Assurance	9
Total number of staff in the Chemical Drug Laboratory	74

Issues noted from this section have been addressed and will be verified during future inspections.

7. Premises

The premises had modern construction and finishing, were tidy and had adequate space. All laboratories that were inspected were air conditioned and had monitoring system for the control of temperature and/or relative humidity in controlled areas. Flexible fume-hood ventilation pendants were installed above each HPLC and other major laboratory equipment and areas for handling of volatile materials such as acid, base and/or organic solvent. The ventilation systems were said to supply clean fresh air.

Issues noted from this section have been addressed and will be verified during future inspections.

8. Equipment, instruments and other devices

NIFDC had over 7,000 pieces of major laboratory equipment and instruments, namely: HPLCs, HPLC-MS, GC, UV, pH, FT-IR, moisture balance, melting point analyser, Nanoparticle analyser, titrator, dissolution tester apparatus, endotoxin detector, analytical balance, and others.

Issues noted from this section have been addressed and will be verified during future inspections.

9. Contracts

The Logistic Service Center was responsible for the periodic evaluation of the vendors on quality, service and other aspects of purchases. The list of qualified vendors was available. The Contract Review Procedure was available. The procedure required that clients would be informed in case of any changes to the testing work that had been agreed upon.

Issues noted from this section have been addressed and will be verified during future inspections.

10. Reagents

Volumetric solutions were prepared in bulk (e.g. 10,000ml bottles) and standardised in a separate building by dedicated staff in the Logistics Service Center and distributed to the different laboratories in the NIFDC. They were properly labelled and stored. A shelf life of 2 to 3 months was given as per recommendations from the Chinese Pharmacopoeia.

Production of purified water was by the nine Millipore Elix systems while the water in the Testing laboratories was generated by Milli-Q units.

Purified water was used to prepare the volumetric solutions but this was drawn from a stainless steel distribution loop that had ordinary elbow connections and stop valve (tap) secured with thread tape. This type of installation has a risk of creating dead legs in which microbial proliferation can take place, thereby making the purified water unsuitable for the intended use. Testing of the purified water was said to be done according to the Chinese pharmacopoeia. Water conductivity was checked once a day.

However, the purified water user point in the Logistics Service Centre was not labelled, hence the inspection team could not confirm if sampling and testing were actually performed every four months as was stated.

The reagents used to prepare the volumetric solutions were not of the analytical grade. For example, Sodium Hydroxide labelled $\geq 96.0\%$ (manufactured by Sinopharm Chemical Reagents Co. Ltd.) was used. The date of first opening of the Sodium Hydroxide reagent bottle was indicated on the bottle.

Issues noted from this section have been addressed and will be verified during future inspections.

11. Reference substances and reference materials

NIFDC is the provider of national chemical reference material of pharmaceutical products. The research and manufacture of national reference material follows the requirements of ISO 17034. Over 4200 Chemical reference standards were provided.

Chemical reference substances for drugs and medical devices were prepared, characterized and distributed by the Research Centre for Reference Standard and Standardization of NIFDC and to other laboratories within China.

There were no adequate controls for the storage of the chemical reference standards that were kept at temperature of $-20^{\circ}\text{C} \pm 3^{\circ}\text{C}$ as the door of the cold room was found intentionally opened, with three people doing some work inside the room, and the temperature had risen to $+14.1^{\circ}\text{C}$, without triggering any visual or audio alarm system.

Issues noted from this section have been addressed and will be verified during future inspections.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Following procedures were reviewed:

- The management of performance of equipment and instruments
- The installation and operation check
- The qualification procedure for HPLC (under 7.0 requalification, once every two years)

HPLC Waters AAH534 IQ checklist version 02 was reviewed. An updated version of IQ checklist was currently in use. In general, the checklist used by the laboratory appeared to be satisfactory. After initial qualification of equipment and instruments, calibration is performed by Beijing Institute of Metrology once every two years and requalification by the NIFDC once every two years. As part of the calibration, pump, flow rate, detector (base line noise, baseline drift), lowest detector concentration, quantitation repeatability and qualitative repeatability, however column oven and gradient profile test was not performed.

National metrology procedure calibration of HPLC should not be more than 2 years.

Issues noted from this section have been addressed and will be verified during future inspections.

13. Traceability

The results of analysis were traceable to the equipment, analyst, and chemical reference materials used during testing. The weights taken on the analytical balances were traceable since certified reference materials (E2 Class standard weighing masses) were used for balance verification and calibration.

Issues noted from this section have been addressed and will be verified during future inspections.

14. Incoming samples

Samples were received in area of adequate space and with 8 receiving stations using a web-based computer software system (<http://lab.nifdc.or.cn/web/>). Sample were logged on the system and three labels printed, and put on the three portions of each sample (one portion sent to the testing lab with a transfer slip, and the remaining two portions sent to the retention store depending on the storage condition of the sample, of either 2°C to 8°C (5°C±3°C) or room temperature but maintained at 17°C±3°C. A temporary storage area, equipped with the above temperature storage facilities, was available near the sample receiving area.

Test request form used for logging the incoming samples did not have provision for recording storage conditions of the samples.

Issues noted from this section have been addressed and will be verified during future inspections.

15. Analytical worksheet

Analytical worksheets were used for recording testing data and information. Print-outs from analytical balances and other small equipment were attached to the Analytical worksheets.

Issuance of analytical worksheets and laboratory notebooks was not controlled. It was noted that analysts were able to print the Analytical worksheets from the electronic document system with no limitation.

The laboratory notebooks were not issued by the QA and were not filled correctly. Some pages had several rows left blank (without crossing them out). The corrections made during recording of results were countersigned but no date was indicated. The completed analytical worksheets and other test records and for each batch or lot of a sample were filed in separate paper folders and taken to the document archive room.

Issues noted from this section have been addressed and will be verified during future inspections.

16. Validation of analytical procedures

The SOP for analytical method validation, verification and transfer was discussed. Under 6.1.2 section of this procedure, verification of analytical methods described in pharmacopoeia are required to verify for its suitability. The procedure was not specific as it did not describe which characteristics to be verified before using methods. It was noted that analytical methods are validated which are developed by the laboratory for Chinese Pharmacopoeia. Under section 7.0 of analytical method transfer, laboratory is required to perform partial analytical method validation. Specific monographs were printed from the Chinese Pharmacopoeia and used directly by the analyst each time testing of a sample was to be done.

Issues noted from this section have been addressed and will be verified during future inspections.

17. Testing

Testing work was carried out according to the Testing Procedure. The major specifications used for the chemical drug analysis are the national drug specifications (including Chinese Pharmacopeia and registration specifications) and imported drug registration specifications (transferred from manufactures' specifications). All of these specifications were said to be approved by NMPA. The Department of General Management was responsible for specifications tracing and release, and the Institute for Chemical Drug Control was responsible for developing the SOP for testing work and record forms to release to each laboratory.

Issues noted from this section have been addressed and will be verified during future inspections.

18. Evaluation of test results

The Out of specification procedure was discussed. It was noted that procedures are revised once every 5 years whereas quality manual is revised once every year. It was claimed that procedures may be revised within 5 years if there is a change in the pharmacopoeia (specification, testing procedure) and requirements. There was no such statement made in the document control procedure. The scope of the procedure was not specific to the extent that tests such as dissolution, content uniformity and in-process tests will follow the OOS procedure or follow the pharmacopoeial requirement. A flow chart was provided as part of the procedure. The procedure was not clear for the number of repeats as it stated, "at least 4 times".

OOS Log sheets were maintained for the physico-chemical tests. It was noted that OOS were reported in the log sheets. From the discussion, it was noted that laboratory does not perform trend analysis. An OOS of Cefradine granules (03051 and 03352) was reviewed for assay content which was below specification. Investigation was done as per the procedure and from the hypothesis analysis, it was concluded that due to insufficient sonication time of 2 minutes, assay resulted low. The sonication time was increased (5 minute) and assay was reported within limit. There was no corrective action taken to revise the procedure so as to ensure consistent implementation of the sonication time. From the review of this OOS, it was also noted that pharmacopoeial procedures are not verified prior to their usage in the lab.

Issues noted from this section have been addressed and will be verified during future inspections.

19. Certificate of analysis

The Certificates of analysis (CoA) were prepared as per the procedure for Preparation of Certificate of Analysis and signed by the authorised persons and dispatched to clients as per the procedure for Dispatch of Certificate of analysis.

Issues noted from this section have been addressed and will be verified during future inspections.

20. Retained samples

Two portions of retention samples were kept in movable storage racks, maintained at temperature of $17^{\circ}\text{C} \pm 3^{\circ}\text{C}$ or as required. Each shelf within the racks was labelled with a bar code sticker, generated by the electronic sample receiving software, but the bar code reader system was not yet implemented. Disposal of the retained samples was done by the Department of General Management, after expired.

Issues noted from this section have been addressed and will be verified during future inspections.

21. Safety

Laboratory Safety Manual was briefly reviewed. Safety international signage system was used. The signs were displayed at relevant locations within the laboratories. Laboratory protective wear e.g. Safety goggles, overcoats, gloves, and fume hood extraction pendants were used.

Issues noted from this section have been addressed and will be verified during future inspections.

Part 3	Conclusion – Inspection outcome
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Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, **Institute for Chemical Drug Control of the National Institutes for Food and Drug Control**, No 31, Huatuo Avenue, Daxing Biomedical Complex, Daxing District, Beijing, 102629, China was considered to be operating at an acceptable level of compliance with WHO GPPQCL Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 5	List of WHO Guidelines referenced in the inspection report
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1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 1.
Short name: WHO GPPQCL Guidelines or TRS No. 957, Annex 1
<http://www.who.int/medicines/publications/44threport/en/>
2. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1
3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/
4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1
5. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf
6. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1
7. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. **Short name: WHO TRS No. 943, Annex 3**
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

8. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.

Short name: WHO TRS No. 937, Annex 4

http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

9. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.

Short name: WHO TRS No. 1010, Annex 10

http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

10. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.

Short name: WHO TRS No. 1025, Annex 4

<https://www.who.int/publications-detail/978-92-4-000182-4>

11. WHO Guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 2011), Annex 13.

Short name: WHO TRS, Annex 13

http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesPreparingLaboratoryInformationFileTRS961Annex13.pdf?ua=1&TRS%20961:%20Annex%2013:%20WHO%20guidelines%20for%20preparing%20a%20laboratory%20information%20file